

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Applicants: C. David SHOOK et al.

Title: UNDERSTOCKING WITH SLEEVE FOR POSITIONING A GEL PAD

Filing Date: June 25, 2003

Serial No. 10/603,643

Examiner: Camtu Tran NGUYEN

Group Art Unit: 3743

Attorney Docket No. 8142A

August 30, 2006

Commissioner for Patents
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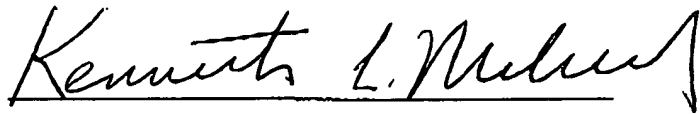
REPLY BRIEF

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BRIEF WAS FAXED TO UNITED STATES PATENT AND TRADEMARK
OFFICE, PATENT OFFICE BOARD OF APPEALS AND INTERFERENCES,
AT 571-273-0053 ON AUGUST 30, 2006.


KENNETH L. MITCHELL, 36873

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KENNETH L. MITCHELL, 36,873

REPLY BRIEF

Dear Sir:

In response to the November 30, 2005 final office action, applicant responds as follows. A Notice Of Appeal from the Examiner to the Board of Patent Appeals and Interferences was filed on February 28, 2006. An Appeal Brief was timely filed by the applicants. *The Examiner's Answer brief was mailed June 30, 2006.*

The new portions of this Reply Brief to the Examiner's Answer Brief are italicized.

REAL PARTY IN INTEREST

The real parties in interest are C. David Shook and David J. Hoy.

RELATED APPEALS AND INTERFERENCES:

There are no other appeals or interferences which will directly affect or have a bearing on the Board's decision in this pending appeal.

STATUS OF THE CLAIMS:

Claims 1-20 have been finally rejected, are under appeal, and are found in the attached appendix. The final office action of Nov. 30, 2005, incorrectly indicates that there are 28 claims. Applicant notes the claim 20 is a duplicate of claim 18 and authorizes the Examiner to cancel claim 20.

STATUS OF AMENDMENTS

No amendments filed subsequent to the final rejection have been made to the claims or the description.

SUMMARY OF THE CLAIMED SUBJECT MATTER

Claim 1 recites a stocking comprising a sleeve and a gel pad within the sleeve. Reference is made to the specification page 3, line 14 et. seq., page 7, lines 1-10, page 8, lines 1-11, and Fig. 4, a view of an understocking illustrating the sleeve in which the gel pad resides.

Fig. 1 is a top view 100 of a gel pad 101 which shows a gel pad with a seal 102 which holds the amorphous gel and the plastic seal border 103 which surrounds the gel pad.

The sleeve is formed by an outer portion 401 and an inner portion 401A. Fig 4. shows an understocking 400 illustrating an opening 402 to a sleeve 708 which

extends around most of the stocking. Sleeve 708 is defined by sock surfaces 401/401A. The understocking may optionally be a compression stocking or a graded compression stocking. The understocking has sufficient elasticity to secure the gel pad 101 in place.

In regard to claim 2, a stocking as claimed in claim 1 is recited wherein the sleeve has an opening for accessing, placing, and positioning gel pad within the sleeve. Fig. 4 illustrates an opening 402 to a sleeve 708 which extends around most of the stocking.

Claim 3 recites and claims a compression stocking comprising a sleeve and a gel pad within the sleeve. Fig. 10 shows the compression stocking 1001 over the entire understocking as well as the sleeve. The sleeve is formed by an outer portion 401 and an inner portion 410A. Stitching 403 secures inner portion 401A to the outer portion 401. End of understocking 404 is a portion of the understocking which is folded over and onto itself to form the portions 401/401A. The compression stocking is placed over the entire understocking. The understocking holds the gel pad in position. Reference is made to the specification page 7 lines 18-21, page 10 lines 16-21, page 11, lines 1-4, page 11, line 21, lines 1-4 and line 21, and page 12, lines 1-2 and lines 9-11.

In regard to claim 4, a compression stocking as claimed in claim 3 is recited wherein the sleeve has an opening in said sleeve for accessing, placing, and positioning the gel pad within the sleeve.

In regard to claim 5, a stocking as claimed in claim 2 is recited wherein the stocking includes a folded portion and a stitched portion 403 to form the sleeve. See specification page 7, lines 8-10.

In regard to claim 6, a compression stocking as claimed in claim 4 is recited wherein the compression stocking includes a folded portion and a stitched portion to form the sleeve.

In regard to claim 7, a stocking as claimed in claim 5 is recited wherein the sleeve extends 360 degrees within the stocking. See Fig. 7 which illustrates the sleeve extending 360 degrees around the stocking. See page 7, lines 11-14 of the specification.

In regard to claim 8, a compression stocking as claimed in claim 6 is recited wherein the sleeve extends 360 degrees within the stocking.

Claim 9 recites a device for treating venous insufficiency comprising an understocking having a sleeve and a gel pad within the sleeve. Reference is made to the specification page 3 lines 14 et. seq. and Fig. 4, a view of an understocking

illustrating the sleeve in which the gel pad resides.

In regard to claim 10, a device for treating venous insufficiency as claimed in claim 9 is recited wherein the sleeve has an opening for accessing, placing, and positioning gel pad within the sleeve. Fig. 4 illustrates an opening 402 to a sleeve 708 which extends around most of the stocking.

In regard to claim 11, a device for treating venous insufficiency as claimed in claim 10 is recited comprising a compression stocking residing over the overstocking. Fig. 10 shows the compression stocking 1001 over the entire understocking as well as the sleeve. The sleeve is formed by an outer portion 401 and an inner portion 410A. Stitching 403 secures inner portion 401A to the outer portion 401. End of understocking 404 is a portion of the understocking which is folded over and onto itself to form the portions 401/401A. The compression stocking is placed over the entire understocking. The understocking holds the gel pad in position.

In regard to claim 12, a device for treating venous insufficiency as claimed in claim 9 is recited wherein a compression stocking resides over the understocking. Fig. 10 shows the compression stocking 1001 over the entire understocking. Reference is made to the specification page 7, lines 18-21, page 10,

lines 16-21, page 11, lines 1-4, and page 12, lines 1-2.

In regard to claim 13, a device for treating venous insufficiency as claimed in claim 9 is recited wherein the understocking includes a folded portion and a stitched portion forming the sleeve. See specification page 8 lines 8-10.

In regard to claim 14, a device for treating venous insufficiency as claimed in claim 13 is claimed wherein the understocking is made from a material selected from the group of nylon, polyester, and cotton. See specification page 8 lines 4-5.

In regard to claim 15, a device for treating venous insufficiency as claimed in claim 13 is claimed wherein the understocking is made from a material selected from an elastic material. See specification page 8 lines 5-6.

Claim 16 recites a method of treating a patient having venous insufficiency comprising the steps of: applying an understocking having a sleeve onto the foot, ankle and leg of the patient; inserting a gel pad into the sleeve; and, positioning the gel pad about the foot, ankle and leg of said patient to apply pressure to reduce the venous insufficiency. See specification page 10 lines 5 et. seq.

In regard to claim 17, a method of treating a patient having venous insufficiency as claimed in claim 16 is recited further comprising the steps of: applying a compression stocking over the understocking and pads. See

specification page 10 lines 13 et. seq. In regard to claim 18, a method of treating a patient having venous insufficiency as claimed in claim 16 is recited wherein the understocking is a compression stocking. See specification page 10 lines 13 et. seq.

In regard to claim 19, a method of treating a patient having venous insufficiency as claimed in claim 17 is recited wherein the understocking is a compression stocking. See specification page 10 lines 13 et. seq.

In regard to claim 20, a method of treating a patient having venous insufficiency as claimed in claim 16 is recited wherein the understocking is a compression stocking. See specification page 10 lines 13 et. seq.

GROUND S OF REJECTION TO BE REVIEWED ON APPEAL

Issue 1. Did the Examiner correctly reject Claims 1-4, 9-12, and 14- 20 under 35 USC 102(b) as being anticipated by Gold (United States Patent 5,187,814)?

Issue 2. Did the Examiner correctly reject Claims 5, 6, and 13 under 35 USC 103 (a) as being unpatentable over Gold (United States Patent 5,187,814)?

Issue 3. Did the Examiner correctly reject Claims 7 and 8 under 35 USC 103 (a) over Gold (United States Patent 5,187,814) and further in view of Lyles (

United States Patent 6,001,122).

Argument

Issue 1 Whether or not the rejection of Claims 1-4, 9-12, and 14- 20 is correct under 35 USC 102(b) as being unpatentable based on anticipation by Gold (United States Patent 5,187,814)?

Claims 1-4, 9-12, and 14-20

Claim 1 and 2

Gold has been studied. Gold does not disclose a gel pad. The word "gel" is not used in Gold. A heater pack is not a gel pad and it does not appear from Gold that the reference is using the terms heater pack to mean a gel pad. Heater pack 34 of Gold is not the claimed gel pad of claims 1, 9, and 16. Claim 2 is dependent on claim 1 and is allowable for at least the reasons that claim 1 is allowable.

Response to Examiner's Answer Brief

The Examiner states nothing new in section 9 of his brief. The Examiner misidentifies the heater pack 34 as the heater pack 30. The actual heater pack in Gold is part number 34 which is held within a device 30 which has sewing stays 33 to the heating element in place. A nylon strap 40 is attached to the sock 400 and is also attached to the device 30 which holds the heater pack. In section 10 of

the Examiner's answer brief he states that United States patent no. 5,984,953 to Sabin (a reference not used in the rejection) relates to a self-heating thermal pack provided through the use of preformed reversibly stiffened gel that alters the rate of exothermic chemical reactions and therefore if the heater pack mentioned in the Gold reference can some how be immediately "directed to the Savin[] thermal heat pack." We are not sure what the Examiner is trying to state here but we believe that the Examiner may be fishing for a basis to equate a heater pack used in Gold to a gel pack which is claimed in claims 1, 7 and 16. Gel pads are moldable. Applicants are entitled to claims 1, 3, and 9 because the claimed structure using a gel pad in a sleeve is new and non-obvious and not anticipated by Gold. Gel pads are moldable. The reliance by the Examiner on a new reference Savin should not be permitted as this is not an obviousness rejection.

The Examiner ignores the difference between a gel pad and a heater pack.

Claims 3 and 9

In regard to independent claims 3 and 9. Gold does not disclose a compression stocking or a stocking of any sort. Gold does not teach a compression stocking. In fact, the words "compress", "compression", and "stocking" are not even used in the Gold disclosure. Compression stockings are known in the art as

set forth in applicant's specification referring to US Patent No. 5,823,195. The sock depicted in Figs. 6 and 7 of Gold is not a compression stocking.

Claims 3 and 9 recite a stocking comprised of the following structure: a sleeve and a gel pad. The Gold reference does not disclose any mention of these terms or structures. As a result, the claims of the instant application do not read on the prior art Gold reference. Gold does not anticipate claims 3 and 9.

Response to Examiner's Answer Brief

The MPEP states in pertinent part,

"2111.02 Effect of Preamble [R3] - 2100 Patentability..... The claim preamble must be read in the context of the entire claim. The determination of whether preamble recitations are structural limitations or mere statements of purpose or use "can be resolved only on review of the entirety of the [record] to gain an understanding of what the inventors actually invented and intended to encompass by the claim." Corning Glass Works, 868 F.2d at 1257, 9 USPQ2d at 1966. If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation

and is of no significance to claim construction. Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999). See also Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997) ("where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention, the preamble is not a claim limitation"); Kropa v. Robie, 187 F.2d at 152, 88 USPQ2d at 480-81 (preamble is not a limitation where claim is directed to a product and the preamble merely recites a property inherent in an old product defined by the remainder of the claim)."

The Examiner, however, in his Answer Brief, section 10, states that he has not accorded the preamble of claim 3 any patentable weight because the preamble was expressed in the body of the claim. This, however, is not true for claim 3 and claims dependent therefrom because the limitation is in the preamble and not repeated in the body and also does not express a property inherent in an old product defined by the remainder of the claim. The citation to Kropa v. Robie by the Examiner is inappropriate and not applicable to claim 3.

Claims 4 and 10

Claim 4 is dependent on claim 3 and is allowable for at least the reason

claim 3 is allowable. Claim 10 is dependent on claim 9 and is allowable for at least the reason claim 9 is allowable.

Claims 11 and 12

Claims 11 and 12 require compression stockings and these simply do not exist in Gold.

Claims 13 and 14

Claim 13 requires an understocking having folded and stitched portions. Claim 14 dependent on claim 13 requires an understocking made from the group of materials selected from nylon, polyester, and cotton. Gold does not disclose the elements or limitations of claims 13 and 14.

Claims 16

Claim 16 is a method claim directed to positioning and inserting a gel pad in a sleeve to position the pad about the foot, ankle, and leg of a patient. Gold does not have the pad or sleeve and therefore does not anticipate claim 16.

Response to Examiner's Answer Brief

The Examiner makes the statement in section 10 of the Answer Brief that "[t]he Gold device would be inherently capable of performing the steps as recited in the method claims." The Gold reference does not disclose in any way the

application of pressure to the foot, ankle or leg of a person to reduce venous insufficiency. Gold does not disclose a gel pad which is positionable within a sleeve. Rather, Gold discloses a stitched in heater which is not moldable and which is not positionable so as to benefit the patient by proper placement. Gold does not anticipate claim 16 and the claims dependent therefrom (claims 17, 18 and 19).

Claims 17

Claim 17 requires the step of positioning a compression stocking over the understocking. This structure is missing from Gold and the method of positioning the compression stocking is also missing in Gold.

Claims 18, 19, and 20

Claims 18, 19, and 20 requires the understocking to be a compression stocking. This structure is missing from Gold and the method of treating a patient is also missing in Gold. Claims 18, 19, and 20 are being argued separately.

As such, claims 1-4, 9-12 and 16 are not anticipated and claims dependent therefrom are not anticipated. Anticipation requires that there be an identity of invention. Anticipation requires that all elements and limitations of the claim are found within a single prior art reference. There must be no difference between the

claimed invention and the reference disclosure. *Carella v. Starlight Archery and ProLine Co.*, 804 F.2d 135, 138, 231 USPQ 644, 646 (Fed. Cir. 1986). *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542, 1549, 220 USPQ 193, 198 (Fed. Cir. 1983). *Kalman v. Kimberly-Clark Corp.*, 218 USPQ 781 (Fed. Cir. 1983).

The instant applications recites the following structure : gel pad and stocking. The Gold reference does not disclose any mention of these terms or structures. As a result, the claims of the instant application do not read on the prior art Gold reference. Gold does not anticipate the device of this application.

Issue 2

Whether or not the Examiner correctly rejected Claims 5, 6, and 13 under 35 USC 103 (a) as being unpatentable over Gold (United States Patent 5,187,814)?

Arguments in regard to Claims 5, 6, and 13

As demonstrated above, Gold does not anticipate claims 1 and 9 from which claims 5, 6, and 13 indirectly depend. Hook and pile connects 441, 442 are not folded or stitched portions. Rather, they are connectors which control/seal the opening for placement of the heater pack. The folded and stitched portions claimed in claims 5, 6, and 13 "bound" the sleeve and are not locks or hooks. See

Specification page 8, lines 5, 8-11. Nor are hook and pile connects 441, 442 compression devices. Rather, they are believed to be Velcro type locks. There is no suggestion in Gold (directed to heater packs in gloves) to modify it to arrive at the invention of a stocking or compression stocking as claimed in claims 5, 6, and 13. Claims 5, 6, and 13 are not obvious in view of Gold.

Response to Examiner's Answer Brief

The Examiner again points to the hook and pile connectors 441, 443 of Gold and wants to equate these somehow to the folded and stitched structure of the claimed invention as set forth in claims 5 and 13. Claims 5 and 13 are not claim fasteners for any purpose. Gold may include a fastener as it has a tethered heater which is tethered by strap 40. Strap 40 and the tethered nature of Gold emphasize the structural and functional differences between Gold and the claimed invention. The heater pack of Gold is sewn in place and is not capable of being placed where it is wanted or needed to apply pressure to a patient's foot, ankle or leg to treat a patient for venous insufficiency. Hook and pile connectors 441, 443 of gold are used to prohibit a person from sticking their foot in the wrong opening as set forth in col. 7 lines 18-39 of Gold.

The Examiner in section 9 of the Examiner's Answer Brief states that the

Gold reference has the "same equivalent for the same purpose as claimed." This is not believed to be an accurate statement of the law with respect to obviousness nor is it literally accurate as stated above.

Issue 3

Whether or not the Examiner correctly rejected Claims 7 and 8 under 35 USC 103 (a) as being unpatentable over Gold (United States Patent 5,187,814) and further in view of Lyles (United States Patent 6,001,122) ?

Arguments in regard to Claims 7 and 8

As demonstrated above, Gold does not anticipate claims 1 and 3 from which claims 7 and 8 indirectly depend. Lyles appears to be a wrap around device with a hot or cold pack wrapped around a stocking.

The word "stocking" is not used in Lyles. The device is not a stocking and it does not extend 360 degrees around the foot of a user. The term "360" does not appear in Lyles. Rather, each closed edge is in the form of a pleat 23. Claims 7 and 8 are not obvious in view of Gold and Lyles.

Additionally, the references Gold and Lyles present teaching which differs from the invention as claimed. Gold discloses a device for heating garments. See Gold Abstract line 1 and Claims 1-14 of Gold. Lyles teaches the use of a bootie

containing at least one thermal pack. Both references teach the use of heat in a garment, neither reference teaches or suggests the use of therapeutic pressure to promote healing of skin ulcers and discolorations. In the instant invention, gel pads are used "to neutralize the elevated internal venous pressure by exerting an equal external compression force." (Spec. Pg. 2 lines 12 et. seq.). The thermal packs in both Gold and Lyles are used to increase heat at the surface of the skin. The references contain no common teaching, understanding, or identification of the problem to arrive at the instant invention as claimed.

MPEP section 2143.01 indicates that the prior art must suggest the desirability of the claimed invention. "Obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either explicitly or implicitly in the references themselves or in the knowledge generally available to one of ordinary skill in the art. 'The test for an implicit showing is what the combined teachings, knowledge of one of ordinary skill in the art, and the nature of the problem to be solved as a whole would have suggested to those of ordinary skill in the art.' Here, it is respectfully suggested that the Examiner is improperly combining the references. There is no basis for combining the references as no teaching, suggestion, or motivation is found in the

references to arrive at the instant invention as claimed.

In *In re Kotzab*, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000) the court held that a “finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of [the claimed invention] to make the combination in the manner claimed” must be made. In the instant application, the Examiner has not identified a specific understanding or principle within the knowledge of the skilled artisan that would have motivated one with no knowledge of the claimed invention to make the combination in the manner claimed. Nowhere does the Examiner identify the artisan given the differences in the problems to be solved, nor does the Examiner explain the motivation for combining the structure of the references.

Further, the references of Gold and Lyles are not properly combinable with the teachings of the instant invention. The heat taught in the references provides a different result on the surface of the skin than pressure as taught in the instant invention.

Response to the Examiner's Answer Brief

The Examiner correctly recites that Lyles includes top and bottom pockets for the reception of heaters therein which slide over the foot of a person.

However, the Examiner does not address the pleats 23 which form the pockets and separate the pockets from one another. Nor does the Examiner address the differences in purpose and function of the references (heating toes) as compared to the claimed invention (treating venous insufficiency).

SUMMARY AND CONCLUSION

Gold has fundamentally different structure than the claimed invention as evidenced by its tethered structure, a heater pack sewn in place (not gel pad positioned in the sleeve), hook style connectors, and the different structural features cited above. Gold is also completely deficient in regard to the claimed process as both the purpose and the structure of the reference is fundamentally different and distinct from the claimed invention. Gold does not disclose a gel pad which is positionable within a sleeve so that the gel pad may be located where needed. The gel pad enables uniform application of pressure where needed.

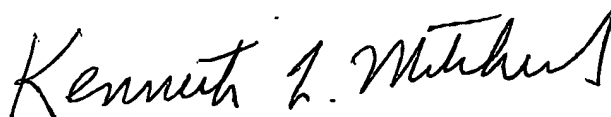
Claims 1-4, 9-12, and 14-20 are patentable over the Gold reference for the reasons stated above. Claims 5, 6, and 13 are patentable over the Gold reference. Claims 7 and 8 are patentable over the Gold reference in view of the Lyles reference for the reasons stated above. Wherefore, it is respectfully requested that the rejection of the claims be reversed and that the same be determined as being

allowable.

FEE

The Commissioner is hereby authorized to charge the deposit account no. 23-3060 in the amount of \$250.00 for the Appeal Fee. If there any additional charges, or any overpayment, in connection with the filing of this appeal brief, the Commissioner is hereby authorized to charge any such deficiency, or credit any such overpayment, to deposit account no. 23-3060.

Respectfully submitted,



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PAD

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CLAIMS APPENDIX

Claims:

- 1. (Original) A stocking comprising a sleeve and a gel pad within said**

sleeve.

2. (Original) A stocking as claimed in claim 1 further comprising an opening in said sleeve for accessing, placing and positioning said gel pad within said sleeve.

3. (Original) A compression stocking comprising a sleeve and a gel pad within said sleeve.

4. (Original) A compression stocking as claimed in claim 3 further comprising an opening in said sleeve for accessing, placing and positioning said gel pad within said sleeve.

5. (Original) A stocking as claimed in claim 2 wherein said stocking includes a folded portion and a stitched portion to form said sleeve.

6. (Original) A compression stocking as claimed in claim 4 wherein said compression stocking includes a folded portion and a stitched portion to form said sleeve.

7. (Original) A stocking as claimed in claim 5 wherein said sleeve extends 360 degrees within said stocking.

8. (Original) A compression stocking as claimed in claim 6 wherein said sleeve extends 360 degrees withing said stocking.

9. (Original) A device for treating venous insufficiency comprising an understocking having a sleeve and a gel pad within said sleeve.

10. (Original) A device for treating venous insufficiency as claimed in claim 9 further comprising an opening in said sleeve for accessing, placing and positioning said gel pad within said sleeve.

11. (Original) A device for treating venous insufficiency as claimed in claim 10 further comprising a compression stocking residing over said understocking.

12. (Original) A device for treating venous insufficiency as claimed in claim 9 further comprising a compression stocking residing over said understocking.

13. (Original) A device for treating venous insufficiency as claimed in claim 9 wherein said understocking includes a folded portion and a stitched portion forming said sleeve.

14. (Original) A device for treating venous insufficiency as claimed in claim 13 wherein said understocking is made from a material selected from the group of nylon, polyester, and cotton.

15. (Original) A device for treating venous insufficiency as claimed in claim

13 wherein said understocking is made from a material selected from an elastic material.

16. (Previously Presented) A method of treating a patient having venous insufficiency comprising the steps of:

applying an understocking having a sleeve onto the foot, ankle and leg of said patient;

inserting a gel pad into said sleeve; and,

positioning said gel pad about said foot, ankle and leg of said patient to apply pressure to reduce said venous insufficiency.

17. (Original) A method of treating a patient having venous insufficiency as claimed in claim 16 further comprising the steps of:

applying a compression stocking over said understocking and pads.

18. (Original) A method of treating a patient having venous insufficiency as claimed in claim 16 wherein said understocking is a compression stocking.

19. (Original) A method of treating a patient having venous insufficiency as claimed in claim 17 wherein said understocking is a compression stocking.

20. (Original) A method of treating a patient having venous insufficiency as claimed in claim 16 wherein said understocking is a compression stocking.

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EVIDENCE APPENDIX

NONE

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RELATED PROCEEDINGS APPENDIX

NONE